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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,770	01/16/2001	Fei Yang	DEX-0113	8352
26259	7590	12/03/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			YAEN, CHRISTOPHER H	
			ART UNIT	PAPER NUMBER

1642

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/700,770

Applicant(s)

YANG ET AL.

Examiner

Christopher H Yaen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 9-13 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/21/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

**Re: Yang *et al***

**Priority Date: 21 May 1998**

1. The amendment filed 9/16/2004 is acknowledged and entered into the record. Accordingly, claims 2-8 are canceled without prejudice or disclaimer, and claims 9-13 are newly added.
2. Claims 1,9-13 are pending and examined on the merits.
3. Claims 1,9-13 are examined on the merits.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

5. The Information Disclosure Statement filed 10/21/2004 is acknowledged and considered. A signed copy of the IDS is attached hereto.

### ***Claim Rejections Maintained - 35 USC § 103***

6. The rejection of claim 1 under 35 USC § 103 (a) is maintained for the reasons of record. Applicant argues that the limitation of "at least two times higher" is a property of the instant invention and that Bandman *et al* do not teach such a limitation. Applicant also argues that Bandman *et al* do not recognize that the determination of expression levels of at least two times higher is a "result effective property" (see page 10 of response). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

Bandman *et al* teaches that the detection of SEQ ID No: 3 is useful for the determination of diseases, and further teach that “relatively high amounts of transcript in biopsied tissue from an individual may indicate a predisposition for the development of the disease” (see col. 35, lines 34-37). Given that the claim is drawn to a method of detecting at least two times higher, wherein at least two times higher can be interpreted as any amount over two times, the detection of “relatively high amounts” falls within the range of at least two times higher. It would be reasonable for one of skill in the art to interpret “relatively high amounts” as those levels that are at least 2 times higher than normal or even 10 times higher than normal. Thus the claimed limitation of at least two times higher despite not being stated by Bandman *et al* would fall within the acceptable and predictable range of the skilled artisan. One of ordinary skill in the art would be motivated to practice the claimed method by determining an expression level of at least two times higher as an indication of neoplastic tissue because this range falls within the range of “relatively high” taught by Bandman *et al*. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

Moreover, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). In the instant case, applicant states that the limitation of “at least two times higher” is a result effective

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property. However, as previously stated, Bandman *et al* also teach that “relatively high amounts” would indicate predisposition to a disease, and therefore Bandman *et al* also recognized that such a determination was critical for the detection of the disease. As such, the Bandman *et al* recognized that not only high amounts but “relatively high amounts” are critical to the determination of a diseased state.

Thus given the that the determination of expression levels falls within the range of relatively high as taught by Bandman *et al*, the motivation and reasonable expectation of success provided by the disclosure of Bandman *et al*, it would be obvious to one of skill in the art to practice a method detecting lung cancer by detecting SEQ ID No: 3. As such, the rejection of claims under 35 USC 103(a) as being obvious over Bandman *et al* is maintained for the reasons of record.

### ***Conclusion***

7. Claim 1 is not allowed. Claims 9-13 appear free of the prior art.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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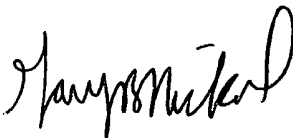
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
November 22, 2004

  
**GARY NICKOL**  
**PRIMARY EXAMINER**